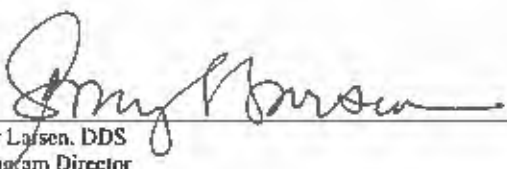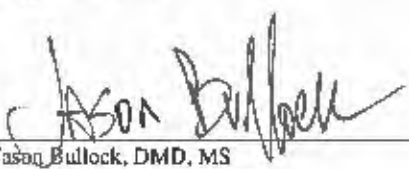Submitted by Stephanie M Price in partial fulfillment of the requirements for the degree of Master of Science in Oral Biology.

Accepted on behalf of the Faculty of the Graduate School by the thesis committee:

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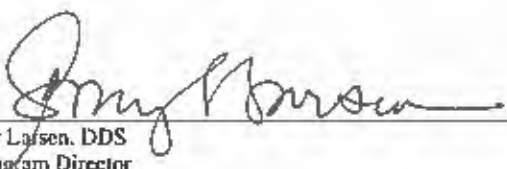The author hereby certifies that the use of any copyrighted material in the thesis manuscript entitled:

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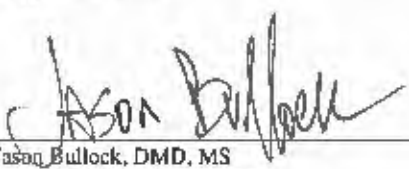
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Evaluating the effectiveness of biomaterial removal from dental implant drills

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ABSTRACT

Multiple studies question the efficacy of cleaning and sterilizing protocols for multi-use dental burs and endodontic files. The US Army, among other institutions, implemented a single use policy for burs and endodontic files; included in this policy are implant osteotomy drills. We hypothesize that our cleaning protocols cannot guarantee complete debris removal thereby supporting the single use drill policy.

This in-vitro study examined 160 Biomet 3i[TM] drills of two configurations imaged with SEM at 30X magnification. Eighty drills were used to conduct osteotomies on a porcine mandible; 40 (positive control) were steam autoclaved and imaged directly and 40 were cleaned using our standardized protocol, steam autoclaved, and then imaged. Eighty drills were used as negative control; 40 were imaged directly from the package and 40 were cleaned using the same protocol, steam autoclaved and then imaged. Four independent observers scored visible debris as a percentage of total drill area on each image. The results were compared using ANOVA post-hoc and Tukey HSD tests.

None of the four groups showed an absence of debris on all drills. Unused and cleaned drills showed on average 18% less debris than used and cleaned drills; however the results were not statistically significant. The scoring system did not differentiate between surgical debris and remnants of cleaning solutions. This initial study does not support a single use policy for dental implant drills. More research is indicated to differentiate surgical debris from solution remnants, to verify results with different cleaning procedures, and to investigate pathogenicity of debris.

Key words: infection control, implant drills, single-use medical equipment

BACKGROUND

In the past 50 years, research studies evaluating the effectiveness of cleaning dental instruments focused primarily on endodontic files and dental burs because of their intricate architecture and frequent use and reuse. Most studies assessed the presence of contamination by comparing either microbial culture or microscopic imaging and concluded that debris cannot be fully removed from endodontic files and dental burs prior to sterilization.[1-12] Evidence shows that burs, files and drills not labeled as "sterile" from the manufacturer contain both organic and manufacturing debris and must be sterilized prior to use.[11,13-16] Because of this both the Department of Veterans Affairs and the US Army have implemented a single use policy for burs and endodontic files and have expanded this policy to include implant osteotomy drills.[17,18] In 2015 the FDA published new recommendations for reusable medical devices giving guidance to manufacturers to validate cleaning protocols.[19]

Threats to complete sterilization include fungi, bacteria, viruses, and prions with average sizes 3-30µm, 1-3µm, 0.02-0.03 µm, and 0.005-0.01µm respectively. A principle of infection control is that instruments should be as clean as possible; we rely on sterilization to remove infectious viability from debris.[20-22] Studies of endodontic files, dental burs, and dental instruments show our current standard of practice utilizing steam sterilization kills fungi, viruses and bacteria.[8,23-31] Prions, associated with Creutzfeldt-Jakob Disease (CJD), are not destroyed by the standard sterilization techniques.[32] Destruction is only confirmed with incineration at 1000°C,[33] although recently enzymatic soak combined with sterilization or plasma sterilization were found to be effective at eliminating prion infectivity.[34,35] The presence of inorganic and organic debris can promote thermal resistance of pathogens and interfere with complete sterilization.[21] Finally, although it is difficult to confirm with evidence, it is possible that inert biological debris itself could potentially cause an inflammatory risk.

There are four basic methods of cleaning dental instruments: presoaking, ultrasonic, automatic washer disinfector, thermal washer disinfector and hand scrubbing- with benefits of each method subject to debate. The addition of an enzymatic presoak shows a statistically significant benefit, although they vary in composition.[1,29,32,36,37] Some studies support the use of ultrasonic cleaners[6] while others failed to find a statistically significant advantage over the washer disinfector,[38] however both are considered a safe alternative to hand scrubbing as there are concerns about percutaneous blood exposure.[21]

Although, there are no published incidents of transmission of a pathogen through an instrument after standard of care sterilization in the dental office, instances of infection control failures are likely under reported.[39] There is one known patient to patient transfer of Hepatitis B in 2001 involving an oral surgery clinic. A subsequent investigation discovered no breakdown in infection control and sterilization protocols. The authors suspected cross-contamination from an environmental surface as the etiology of the transmission.[40] A second instance of Hepatitis B transmission occurred in 2009 associated with a portable dental clinic with both volunteers (2) and patients (3) infected. Again, an investigation was unable to determine the exact cause of the transmission, although failure to sterilize headpieces and failure to wrap sterilized instruments were cited as potential causes.[41]

The trend towards single use instruments in the United States was fueled by an instance in 2013 of bacterial transfer of E. Coli to 39 patients exposed to a single duodenoscope in Illinois (CDC HICPAC minutes). Since then, recommendations have been made by both the CDC (facilities) and FDA (manufacturers) for multiple use medical instruments which are critical, i.e. exposed to mucosa or vascular tissue, and have intricate architecture making them inherently difficult to clean. In addition to being cleaned, dudenoscope sterilization is sometimes verified with flushing or sampling and culturing techniques (CDC HICPAC). However limitations to culturing both human and technological in addition to expense, make this a difficult standard of care. Manufacturer procedures should be validated using quantitative test methods using extraction and DNA recovery[19]; however no published studies assess the cleanliness of dental instruments using this method. In the United Kingdom, single use endodontic and dental burs has been more public due to the confirmed case, although again, not dentally related, of prion transmission resulting in a variant of CJD.[42,43] There is no evidence of implant complications as a direct result of contaminated (or reused) drill surfaces.[44]

A cost analysis of single use versus reusable drills for the Veterans Administration is estimated at $100 per implant. This is based on a government price and data that supports an average of two implants placed in a patient per surgical session.[17] Army clinics worldwide place an average of 1.64 implants per visit (T Oringderff, oral communication, APR 2016); combined with the additional use of a starter drill and the possible use of a dense bone tap, the expense approaches approximately $200 per implant for a total of $1.2M year.

A single study similar to this one, investigated the cleansability of lumen free implant drills by exposing them to radioactively marked blood and concluded that predictable complete removal of all blood is impossible and therefore implant drills should be regarded as single use.[45] This study did not use enzymatic cleaners or a washer disinfector. In this study we replicated our current cleaning and sterilizing techniques to validate the US Army single use drill policy and as a pilot study to assess the need for single use implant drills. This study is unique in that it assesses the adequacy of a current standard protocol to determine if used drills can be returned to the same level of cleanliness as unused drills.

MATERIALS AND METHODS:

Eighty multiple use twist drills (2.0mmX10mm) and 80 multiple use quad shaping drills (3.25mmX10mm) (Biomet 3i™, Palm Beach Gardens, FL) were chosen for this investigation. They are externally cooled, surgical stainless steel and have the smallest grooves which we theorized would be the hardest to clean. All drills were received unsterile from the manufacturer, placed in the surgical trays in groups of 40 (20 twist and 20 quad shaping) with ungloved hands. The drills were divided into the following groups: Group A, positive control, (Cleaned, sterilized and used for porcine osteotomy, then sterilized and imaged); Group B, experimental (Cleaned, sterilized and used for porcine osteotomy, then cleaned again, sterilized and imaged); Group C, uncleaned negative control (Placed into tray and imaged); and Group D, cleaned negative control (Placed into the tray, cleaned, sterilized and imaged).

Eighty drills for Group A and B were used to perform 40 total osteotomies in a porcine mandible (sacrificed 12 hours prior). After each osteotomy (first twist then quad shaping), the drills were placed in a stainless steel surgical cup of sterile saline until all osteotomies were completed. Drills were returned to

two surgical trays (20 of each type in each tray) and placed on a shelf on the dirty side of the sterilization suite for 75 minutes prior to cleaning protocol as per our usual worst case clinic operational routine.

Forty drills for Group C were removed from manufacturers packaging, placed in the surgical tray, and sent immediately for imaging. Once Group C returned, the drills were relabeled as Group D. They were cleaned and sterilized and returned for imaging.

Each cleaning iteration followed the same procedure using both ultrasonic and thermal washer disinfector. The ultrasonic (Elmasonic S300,Singen, Germany) was prepared by rinsing, filling with fresh water, and run at 80ºC for 45 minutes with enzyme tablets (Maxizyme, Henry Schein, Melville, NY). The ultrasonic was then emptied, rinsed and refilled with fresh water. Each tray was placed individually in the ultrasonic at 80ºC for 45 minutes with detergent solution (MPUS Plus, Dentronix, Cuyahoga Falls, OH). Ultrasonic cleaning was verified with Sonocheck[TM] (Healthmark Industries, Fraser, MI). Following ultrasonic, the trays were rinsed with fresh water for 2 min and placed in a 50min thermal washer disinfector cycle (Getinge86, Rochester, NY), which automatically dispenses enzymatic, detergent and pre-sterilization lubricant solutions. The wash cycle was verified with a TOSI[TM] washer test (Healthmark Industries, Fraser, MI). The drills were placed in the vacuum steam autoclave for 5 minutes 273ºF with 20 minute dry time (Getinge, Rochester, NY). Both the Bowie-Dick (Assure S.M.A.R.T., Getinge, Rochester NY) and biological spore test (Attest[TM], 3M[TM], Maplewood, MN) verified functionality of the steam autoclave.

The drills were packaged and sent for scanning electron imaging (SEM) at 30X. The drills were kept covered except during imaging and the microscopist did not touch any part of the surface to be imaged. Each image was divided into squares of approximately 300µm each with the number of squares varying depending on the amount of drill imaged. Squares that contained $< \frac{1}{4}$ drill surface were eliminated from view. The 160 drill images were observed and scored by four independent observers in the same randomized order. Their scores represented number of squares with debris divided by the total number of squares.

RESULTS

No drill groups were completely free of debris. The F test is highly significant indicating that at least one pairwise comparison is significant ($F (3,156) = 199.36$, $p < 0.001$). As expected, pairwise comparisons showed that B is significantly lower than A ($p < 0.0001$).

In other pairwise comparisons, D is significantly lower than C ($p < 0.0001$), additionally B was not significantly different from C; ($p = 0.09$). Therefore new drills that are cleaned and sterilized are statistically cleaner than used drills that are cleaned and sterilized, and cleaned and sterilized used drills are statistically no different than new drills from the package.

A t-test demonstrated statistical inconsistency between drill sets D1-D5 and drill sets D6-D8. This is likely due to a variation in the environmental conditions and the settings used in the SEM. The images from sets D6-D8 are clearer than the images from sets D1-D5 and the data from sets D6-D8 are more supportive of the statistically significant difference between groups D and B.

DISCUSSION

A limitation of visual assessment with SEM is that surface irregularities, for example the matt surface of the twist drill and the central groove of the quad shaping drills make it difficult to differentiate extent of debris. A second limitation of the SEM is that it is difficult to differentiate surgical debris from remnants of cleaning solutions. We hypothesized the milky white surface irregularity found on various drills of both groups B and D to be pre-sterilization lubrication added in the final stage of the washer disinfector. Future research could disable this component of the washer disinfector; rinse the drills with alcohol following the washer disinfector, or use environmental scanning electron microscope (ESEM) to more specifically identify the chemical components of the debris. This debris interpretation could contribute to the large standard deviation found in all groups.

In this study the standard deviations were large in all four groups. Although observer interpretation could be a contributing factor, large standard deviations are also found in other

investigations with different study methodologies. The large deviation was also found in used and uncleaned drills which rules out individual variation from the cleaning as a cause. We hypothesize that manufacturing variances could result in a large variation in surface smoothness, thus a variation in debris retention.

The presence of debris on all drill groups in this study raises a question as to the presence of debris on other reused instruments with similar architecture- i.e. bone files, operative hand instruments, and periodontal scalers. It is unlikely that the debris contains viable bacteria, viruses or fungi- particularly in groups B-D which have more limited levels of debris because of the pressure/temperature levels confirmed by the spore and Bowie- Dick leak test. A critical step a in cleaning is the visual observation of debris; however, even if debris is not visible, it is likely there as shown by the presence of debris on clean but unused drills. The quantity of debris which potentially interferes with sterilization is difficult to determine. Despite the discovery of debris on both new and used drills and the theoretical ubiquitous presence of debris, early failure of implants is remarkably low at 2%.[46]

The magnification of the drills in this study, 30x, was not large enough to identify specific pathogens. All drills were imaged at 60x (drill tip and mid drill), and several images were obtained at 1000x; these images were not used in the study. Bacteria, the largest pathogen, are barely visible on a 1000x image, and the field of view is limited to only the drill tip. We felt that analyzing more of the drill surface, especially as this is an initial study, would provide more meaningful results. One of the experimental drill images at 30x was lost and reconstructed and reduced in size using two segments of 60x images of the same drill. The 1000x images, all taken of unused and cleaned drills, showed visible surface defects- larger in size then a potential bacterium. These defects may be polished out during initial use, or these surface defects may be responsible for the retained debris in used drills. This is an area for future research as we did not obtain any 1000x images of used drills to compare.

Dental clinics use different cleaning and sterilization protocols- all within the standard of care- based on their resources, size and mission. Institutional cleaning equipment like the thermal washer disinfector used in this study may not be available in smaller clinics. While hand scrubbing is not recommended at our institution, it may be more feasible in smaller clinics. Given these variations, it is difficult for manufacturers to establish protocols which practically and universally guarantee the ability to return a used drill to its unused state. Our protocol does not follow the manufacturer's instructions. For example, the drills were soaked in the 0.9% sterile saline solution used in the surgery, whereas the manufacturer recommends a neutral pH. Saline can have a pH 4.6-5.5.[47,48] This slight acidity may enhance the ability to retain debris or modify the surface making it appear to have debris. A worthy future investigation could be used to verify the cleaning protocols as defined by the manufacturer.

FDA requires manufacturers to produce procedures for cleaning an dusers to follow them, in this study we did not follow the published 3i directive.

CONCLUSION AND FUTURE RESEARCH

Although there was not a statistically significant difference between the experimental (used and cleaned) drills and the negative control (unused and cleaned) the average debris on the used and cleaned drills was higher than the average on the unused and cleaned. These results should be expanded with a second quantitative analysis- potentially DNA recovery.

Future research should include varying the cleaning methods; potentially including neutral pH proteolytic enzymatic soak at the surgical table, the use of alcohol following the washer disinfector to remove pre-sterilization lubricant, and repeating the experiment using Nobel Biocare or other implant systems.

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